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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,777

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Franciscus Marinus De Groot

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EXAMINER

KOSACK, JOSEPH R

ART UNIT

PAPER NUMBER

1626

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,777	Applicant(s) DE GROOT ET AL.	
	Examiner Joseph R. Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,7-10,12,14-25,31-43,45-51,53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 is/are allowed.
- 6) ☒ Claim(s) 4,7-10,12,14-25,31-42,45-51,53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/29/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 4, 7-10, 12, 14-25, 31-43, 45-51, 53, and 54 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 29, 2009 has been entered.

Information Disclosure Statement

The Information Disclosure Statement filed on June 29, 2009 has been considered by the Examiner.

Election/Restrictions

The Applicant has proposed a different core structure and asked the Examiner to consider that core structure. After consideration, the Examiner agrees to expand the search to encompass the subgenus of compounds proposed by the Applicant. Therefore, previously withdrawn claims 8-10, 12, 15, 20-25, 35-42, and 50 are rejoined and are considered in the instant office action.

Previous Claim Objections

Claims 4, 7, 13-14, 16-19, 31-34, 43, 45-49, 51, 53, and 54 were previously objected to for containing elected and non-elected subject matter.

The claims no longer contain non-elected subject matter, and the objection is withdrawn.

Previous Claim Rejections - 35 USC § 112

Claims 4, 7, 13-14, 16-19, 31-34, 45-49, 51, 53, and 54 were previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Applicant has amended the term to be an "enzymatically removable specifier."

However, with the extreme breadth that the generic term "specifiers" covers, a representative number of species is required in order to show possession of the generic term to the full scope claimed, even with the specifier amended to be an enzymatically removable specifier. The rejection is maintained except for those claims expressly cancelled by the Applicant and for claim 43.

The term "leaving group" in claims 4, 7, 13-14, 16-19, 31-34, 45-49, and 51, 53, and 54 is used by the claim to mean "a drug", while the accepted meaning is "a group that is expelled during a substitution reaction such as halides, sulfonamides, alkoxides, etc...." The term was previously found to be indefinite because the specification does not clearly redefine the term.

The Applicant has amended the term to be a therapeutic or diagnostic moiety. As the terms are being used consistent with their accepted meanings, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 7-10, 12, 14-25, 31-42, 45-51, 53, and 54 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, compounds containing specifiers and methods of using them are claimed.

Applicant is reminded of the written description guidelines set out by the USPTO in MPEP 2163:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

When a chemical genus is claimed, the written description requirement is normally satisfied with a generic chemical structure that is drawn out such that the core structure is clearly shown. A review of the disclosure contains examples (claim 43) which only show an extremely small and related subset and not the large and extensive

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claimed genus. While the genus is described by a generic formula in claim 4, the generic formula is not sufficiently detailed to show that the Applicant was in possession of the full scope of the claimed invention at the time of filing. Namely, that there are no explicit definitions of "specifiers" provided within the specification. Additionally, there is little structure/function data provided to show that the Applicant in fact possessed the entire claimed genus at the time of filing. Therefore, the "representative number of species" standard is used to determine whether the claims are adequately described.

MPEP 2163 goes on to describe what a "representative number of species" is:

What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, para. 1.

As the species described in the specification do not cover the entire genus such that it is a representative sample of the genus, the claims do not meet the written description provision of the first paragraph of 35 U.S.C. 112.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7-10, 12, 14-25, 31-42, 45-51, 53, and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 4 has two separate definitions for "P" and it is unclear which definition is to be used: the definition on the top of the second page of the claims or the definition on the bottom of the second page of the claims. Appropriate correction is required.

Additionally, independent claim 4 contains substituents G, H, I, K, L, M, N, and O, but does not contain any definitions for the terms anymore. Even if the substituents are absent, each variable must be defined in the claim. It is suggested that the Applicant remove the terms from the structure.

As claims 7-10, 12, 14-25, 31-42, 45-51, 53, and 54 are dependent off of claim 4, those claims are rejected as well.

Conclusion

Claims 4, 7-10, 12, 14-25, 31-42, 45-51, 53, and 54 are rejected. Claim 43 is currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/
Examiner, Art Unit 1626